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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,910	03/30/2004	David Milton Hadley	330498002US	9281
25096	7590	03/16/2006		
PERKINS COIE LLP PATENT-SEA P.O. BOX 1247 SEATTLE, WA 98111-1247			EXAMINER BERTRAM, ERIC D	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/815,910

Applicant(s)

HADLEY ET AL.

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 19, 25-29, 33-36 and 40-44 is/are rejected.
- 7) ☒ Claim(s) 17, 18, 20-24, 30-32, 37-39 and 45-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/04 and 2/2/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 8/11/2004, 8/20/2004, and 2/2/2006 were filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the margins are not acceptable in fig. 1B, and there are other problems with lines, numbers, letters and characters in multiple figures. Please see the attached Notice of Draftsperson's Patent Drawing Review for further details. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 5, 25, 33 and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10 of copending Application No. 10/816,549, claim 21 of copending Application No. 10/815,290 and claims 1, 2 and 23 of copending Application No. 10/816,561. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods as disclosed are obvious variants of each other, and the apparatus claims disclose identical structure with the only difference being the instructions loaded into the computer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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After reviewing the specification, the Examiner cannot find a disclosure of reducing the number of data points by a factor of between 5 and 30.

Claim Rejections - 35 USC § 103

7. Claims 1-4, 6-13, 15-16, 19, 25-29, 33-36 and 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al. (US 5,921,940, hereinafter Verrier) in view of Brewer et al. (US 5,555,888, hereinafter Brewer). Verrier discloses a method for analyzing T-wave alternans from ECG signals with processor 904, made manifest by applying stress to a subject (see Abstract). Verrier describes identifying T-waves from the ECG signal, and then differencing temporally adjacent T-waves in order to create a data set representing a final alternan estimate waveform (Col. 14, line 39 and Col. 16, lines 15-25). Verrier also describes a method for “smoothing” the estimates by using a high pass digital filter in order to remove respiration artifacts, or disturbances, from the signal (Col. 16, lines 35-41). Once the disturbances have been removed, the result is a final alternan waveform. Verrier does not, however, disclose maintaining alternan polarity of the difference between T-waves. Attention is directed to the secondary reference of Brewer, that discloses differencing temporally adjacent pairs from the cardiac cycle, while maintaining the polarity, as shown in figure 12 (Col. 9, lines 37-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant’s invention to modify the method of Verrier by maintaining the polarity of the difference between temporally adjacent signals in order to create an accurate representation of an alternan estimate.

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8. Regarding claims 6-9, Verrier teaches that the T-wave is found by identifying portions of the ECG signal that includes the entire duration of the T-wave, including the onset and conclusion of the wave (Col. 14, 37-39). Then, a plurality of these segments are aligned into "B" time divisions (Col. 14, lines 40-42).

9. Regarding claim 10 and 11, Verrier describes removing premature beats by using a fixed criteria. It would be obvious to one of ordinary skill in the art that this fixed criteria would be a beat estimate, since actual beats are compared to the estimate to determine if the beat is premature. Since whether or not a beat is premature is based on time, it would also be obvious that the estimate comprises a time-window definition. Verrier further describes choosing a best estimate to identify a T-wave (Col. 14, lines 35-39).

10. Regarding claims 13, 16, 28, 29, 36, 43 and 44, Verrier teaches establishing subsets consisting of M samples, where M is the number of beats occurring during a single respiratory cycle, and then averaging these cycles in order to eliminate respiratory effects on the estimate (Col. 16, lines 42-44).

11. Regarding claim 19, Verrier discloses taking the absolute value of the difference estimate in order to correct reversals in polarity (Col. 16, lines 23-25).

12. Regarding claim 25, Verrier does not disclose sampling the signal at a rate greater than 2000 samples per second. However, in the specification, the applicant states in paragraph [0057] that choosing a sampling rate of greater than 2000 Hz is due to the fact that the Nyquist frequency of the raw ECG data is 1000 Hz. It is well known in the art that one must sample at a rate that is more than twice the Nyquist frequency in

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order to create a faithful reproduction of the signal (Nyquist-Shannon Sampling Theorem).

13. Regarding claims 27, 35 and 42, Equation 8 in Col. 16 shows a data subset defined by " $X(n)-X(n-1)$ " which is then represented by $Y(n)$.

Allowable Subject Matter

14. Claims 17, 18, 20-24, 30-32, 37-39, and 45-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Eric D. Bertram
Examiner
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EDB